

REMARKS

After the foregoing amendment, Claims 1, 4 – 9, 18 – 20, 22 – 26, 28, 35 – 39, 41, 43 – 44, 47 – 51, 53 – 57, 60 – 63, and 65 are pending in this application. By way of the foregoing amendment, Applicant cancels Claims 27 and 45 without prejudice, and amends Claims 1, 19, 20, 22 – 28, 35 – 39, 41, 44, 47 – 51, and 65 without prejudice. Support for the amendments can be found at page 6, lines 5 – 16, page 31, lines 5 – 25, and examples 7, 8, and 24. Applicant submits that no new matter has been introduced into the application by these amendments.

Claim Rejections - 35 USC §102

The Action rejects Claims 1, 4 – 9, 18 – 20, 22 – 23, 25 – 28, and 57 as anticipated by Mroczkowski (WO 90/053000). Claim 27 is canceled by way of the foregoing amendment.

Claim 1, as amended, recites:

A system for assaying one or more targets in a sample comprising:

(a) an assay device having one or more assay sets; each of the assay sets comprising at least two electrodes, a substrate, and a recognition moiety, the at least two electrodes positioned on the substrate and separated by a gap, the recognition moiety positioned in the gap and bound to the substrate, and the recognition moiety capable of specific binding to a component of one of the one or more targets, wherein the one of the one or more targets is selected from the group consisting of a bacterium, a virus, and a cell;

...

(c) reagents comprising *nucleation-center forming entities capable of binding to said one or more targets*, metal ions and a reducing agent; and

... wherein the system is adapted to allow combination of the assay device, the sample, and the reagents, wherein *a respective component and a respective one of the recognition moieties form a respective complex if the respective component is present in the sample and the nucleation-center forming entities can bind to the one or more targets*; and in the presence of the metal ions and the reducing agent, metal is deposited on the nucleation-center forming entities on the respective complex and the deposited metal can form a conductive bridge between the respective one of the at least two electrodes, and

wherein the metal ions in the presence of the reducing agent on the assay device are metastable so that *metal deposition does not take place unless at least one of the nucleation-center forming entities is present*.

Underline and italic emphasis added. As recited, the respective recognition moieties form respective complexes with specific respective ones of the one or more targets. But the nucleation-center forming entities bind to the "one or more targets," rather than to a specific one of said one or more targets. Further, the system is adapted to allow binding of the nucleation-center forming moieties only if at least one of the one or more targets is present, and a conductive bridge is formed only where the entities are bound. Finally, if at least one of the one or more targets is not present, the nucleation-center forming entities will not be present and metal will not be deposited to form the conductive bridge.

In contrast, the cited passages of Mroczkowski cited at pages 6 – 7 of the Action disclose a system where a metal is attached to a target by the action of a recognition moiety. For example, the Mroczkowski system outlined with respect to figure 1 detects a target antigen through binding of a metal-labeled recognition moiety to the target antigen.

Further examples in Mroczkowski require the use of two recognition moieties: 1) a first bound to the diagnostic element, and 2) a second carrying a metal label. The first recognition moiety specifically binds to a target, which is thereby bound to the diagnostic element. And the second recognition moiety specifically recognizes the single target, rather any type of target in the sample. See, for example, page 10, lines 7 – 23 in which the first and second recognition moieties are antibodies that recognize a specific single antigen. Also, see page 10, line 24 – page 11, line 4 in which the first recognition moiety is an antigen that binds an antibody target, and the second recognition moiety is a second antibody that specifically binds the first antibody. In each of these examples, the agent that could be referred to as a “nucleation-center forming entity” is not bound to any targets in the sample but only to a specific target. In contrast, the present invention is based on the use of a single recognition moiety for each target. Further, the present invention relates to a “nucleation-center forming entity,” which is separate from the single recognition moiety.

The Action cites page 15, lines 5 – 9, page 18, lines 22 – 31, and page 25, lines 12 – 29 as passages where Mroczkowski discloses or teaches a “nucleation-center forming entity.” However, these passages deal with an antibody labeled with gold particles. As set forth above, Claim 1, as amended, recites that “nucleation-center forming entities” bind to the “one or more targets.” In this light, these Mroczkowski passages disclose an “antibody recognition moiety that is labeled with a metal,” rather than “nucleation-center forming entities,” as recited in claim 1, as amended.

Claims 4 – 9, 18 – 20, 22 – 23, and 57 depend from and include all of the elements of Claim 1. Independent Claims 25, 26, and 28, as amended, recite a similar relationship between the recognition moieties, nucleation-center forming entities, and targets as in Claim 1. Applicant respectfully requests withdrawal of the rejection of Claims 1, 4 – 9, 18 – 20, 22 – 23, 25 – 26, 28, or 57 as anticipated by Mroczkowski.

Claim Rejections - 35 USC §103

The Action rejects Claims 24, 43 – 45, 47 – 51, 55 – 56, and 65 under 35 U.S.C. §103 as obvious over Mroczkowski in view of Hollis (U.S. patent No. 5,653,939). Applicant believes that Hollis does not remedy the deficiencies of Mroczkowski outlined above, and respectfully requests withdrawal of the 35 U.S.C. §103 rejection of Claims 24, 43 – 45, 47 – 51, 55 – 56, and 65 under 35 U.S.C. 103 as obvious over Mroczkowski in view of Hollis.

Claim Rejections - 35 USC §103

The Action rejects Claims 35, 37, 38, and 41 under 35 U.S.C. §103 as obvious over Mroczkowski in view of Olsen (U.S. patent No. 5,614,832). Applicant believes that Olsen does not remedy the deficiencies of Mroczkowski outlined above, and respectfully requests withdrawal of the 35 U.S.C. §103 rejection of Claims 35, 37, 38, and 41 under 35 U.S.C. 103 as obvious over Mroczkowski in view of Olsen.

Claim Rejections - 35 USC §103

The Action rejects Claims 36, 53 – 54, and 60 – 63 under 35 U.S.C. §103 as obvious over Mroczkowski in view of Olsen and Hollis. Applicant believes that neither Olsen nor Hollis, alone or in combination, remedy the deficiencies of Mroczkowski outlined above, and respectfully requests withdrawal of the 35 U.S.C. §103 rejection of Claims 36, 53 – 54, and 60 – 63 under 35 U.S.C. 103 as obvious over Mroczkowski in view of Olsen and Hollis.

Claim Rejections - 35 USC §103

The Action rejects Claims 39 under 35 U.S.C. §103 as obvious over Mroczkowski in view of Hollis and Olsen. Applicant believes that neither Hollis nor Olsen, alone or in combination, remedy the deficiencies of Mroczkowski outlined above, and respectfully requests withdrawal of the 35 U.S.C. §103 rejection of Claim 39 under 35 U.S.C. 103 as obvious over Mroczkowski in view of Hollis and Olsen.

Conclusion

If the Examiner believes that any additional matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing amendment and remarks, Applicants respectfully submit that the present application, including claims 1, 4 – 9, 18 – 20, 22 – 26, 28, 35 – 39, 41, 43 – 44, 47 – 51, 53 – 57, 60 – 63, and 65, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

Eichen et al.

By /Douglas J. Bucklin/
Douglas J. Bucklin
Registration No. 51,208

Volpe and Koenig, P.C.
United Plaza, Suite 1600
30 South 17th Street
Philadelphia, PA 19103
Telephone: (215) 568-6400
Facsimile: (215) 568-6499

DJB/dmp